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10/730,029	12/09/2003	Zhen Fang Fu	033304-021	3231

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EXAMINER
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SALVOZA, M FRANCO G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/730,029

Applicant(s)

FU, ZHEN FANG

Examiner

M. Franco Salvoza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 01/13/05, 03/11/05.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Claims 2-62 were canceled. Claim 1 is pending and under consideration.

#### ***Specification***

The disclosure is objected to because of the following informalities: References to U.S. patent applications such as 10/199,204 must reflect their current status, such as if the cases have been patented. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites a mutant rabies virus comprising a rabies virus N protein, wherein said N protein is not phosphorylated.

Thus, the claim reads on any mutant virus comprising a rabies virus N protein, wherein said N protein is not phosphorylated at any position or sites along the N protein.

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The following quotation from section 2163 of the Manual of Patent Examination Procedure is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus... See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Thus, when a claim covers a genus of inventions, the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed. In this case, the specification has not provided sufficient examples or structural characteristics regarding dephosphorylation of N proteins of the rabies virus to provide adequate support for the entire scope of the genus claimed. The specification lacks a description of which additional positions or sites may be dephosphorylated or any other modifications to the viral genome that would prevent phosphorylation to still retain and maintain adequate structural and functional characteristics leading to a decrease in viral replication or increase in RNA binding.

The specification does not identify the minimum regions or specific positions where the respective N proteins are to be dephosphorylated, except for N position 389. While the specification discloses substitution of other amino acids for serine at N position 389 (as well as mutations at glycoprotein G) (specification, p. 16), no further information beyond this example is

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provided by the disclosure as to how to properly dephosphorylate the N protein of rabies virus to provide support for the entire scope of the claim. Thus, the claims are drawn to a genus of mutant rabies viruses comprising dephosphorylated nucleoproteins without a supporting disclosure of the full scope of where such dephosphorylations can specifically be made, and the claims do not require that the dephosphorylated nucleoprotein possess any conserved structure. Furthermore, the claimed genus would include rabies virus having modifications changing N-protein structure to make serine-389 inaccessible to the phosphorylating enzyme as suggested on p. 15 of the specification. However, there is no descriptive support teaching such modifications, or any other modification other than substitution of S-389 resulting in live mutant viruses lacking phosphorylation of the N protein. When a claim covers a genus of inventions, the specification must provide written description support for the entire scope of the genus.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

In this case, the only factor present in the claims are recitations to a genus of mutant rabies viruses comprising dephosphorylated N protein. There is not identification of any particular portion of the N protein structure that must be conserved or interacting sites that would accept or inhibit dephosphorylation. There is one example, but only one. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written support of the claimed genus.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Clark et al. (1976).

Claim 1 recites a mutant rabies virus comprising a rabies virus N protein, wherein said N protein is not phosphorylated.

Clark et al. discloses a mutant rabies virus (p. 1918).

Applicant's disclosure recites a period during which the N protein of the mutant rabies virus is not phosphorylated (specification, p. 52), thus rendering the teaching of a mutant rabies virus as in Clark et al. anticipatory of the mutant rabies virus recited in claim 1.

An amendment to the structure of the mutant rabies virus recited in claim 1 requiring modification at position 389 of the rabies virus N protein or a substitution of another amino acid at said location for serine would overcome this rejection.

***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957);

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and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 1 rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,706,523. This is a double patenting rejection.

### ***Conclusion***

Pertinent art to be cited of record (as disclosed in IDS filed Dec. 5, 2003):

Yang et al., "Phosphorylation of Rabies Virus Nucleoprotein Regulates Viral RNA Transcription and Replication by Modulating Leader RNA Encapsidation," Journal of Virology, Vo. 73, No. 2, 1661-1664 (1999). Yang et al. is cited as close relevant prior art since it teaches isolated rabies virus N proteins that are dephosphorylated resulting in a decrease of transcription and viral replication. However, Yang et al. does not disclose a mutant rabies virus comprising the dephosphorylated N protein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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April 28, 2006



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